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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jeffrey C. Garland

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

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1797

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DELIVERY MODE

07/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,853	Applicant(s) GARLAND ET AL.	
	Examiner WILLIAM H. BEISNER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. Applicant is advised that should claims 1-19 be found allowable, claims 40-58 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 12, 13, 15-20, 23-27, 31, 32, 33, 40-46, 51, 52 and 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Dell et al.(US 5,385,821).

With respect to claims 1 and 40, the reference of O'Dell et al. discloses an apparatus or system for holding an organ or a tissue for at least one of perfusion, storage, diagnosis and transport of the organ, comprising: an organ or tissue transporter (94); a portable housing (98) having one or more heat transfer surfaces (outer surface of housing (98)); a compartment (96) within the transporter (94) having one or more heat transfer surfaces (110) arranged to transfer heat between a cooling source (106) in said transporter and at least a part of one of the one or

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more heat transfer surfaces of the portable housing (98); an organ or tissue supporting surface configured to support an organ or tissue within said portable housing (the bottom of housing (98) or elements (15) (13)), wherein the portable housing is configured to be received by the transporter and wherein at least a portion of at least one of the one or more heat transfer surfaces of the compartment is in contact with at least a portion of at least one of the one or more heat transfer surfaces of the portable housing to allow effective heat transfer to or from the contents of the portable housing (See Figures 9 and 10 and column 8, line 36, to column 9, line 16).

With respect to claims 2, 18, 19, 41, 57 and 58, the cooling source includes ice packs (106).

With respect to claims 3 and 42, the housing (98) is configured to support the organ while allowing effluent medical fluid to pass through the organ or tissue (See Figures 1-3).

With respect to claims 4, 7, 43 and 46, the compartment and housing have substantially complementary configurations (See pocket (107)).

With respect to claims 5, 6, 44 and 45, the majority and/or substantially of the heat transfer surface of the compartment contact the majority and/or substantially of the heat transfer surface of the housing (See Figures 9 and 10).

With respect to claims 12, 13, 51 and 52, the housing (98) includes openings in element (20) that are capable of having tubing pass through the openings.

With respect to claims 15, 16, 31, 54 and 55, element (35) of O'Dell et al. is capable of functioning as a handle and is accessible when the housing is mated with the container (See Figures 9 and 10).

With respect to claims 17 and 56, the bottom of housing (98) is liquid tight.

With respect to claim 20, the device is constructed and used so as to transport an organ or tissue (See column 3, line 66, to column 4, line 12).

With respect to claim 23, the organ is connected to a tube (15).

With respect to claims 24-26 and 33, the cooling source includes ice packs (106).

With respect to claim 27, the compartment and housing have substantially complementary configurations (See pocket (107)).

With respect to claim 32, the bottom of housing (98) is liquid tight.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 8-11, 28, 29, 34, 35 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dell et al.(US 5,385,821) in view of either Douglas-Hamilton (US 4,530,816) or Peterson (US 3,810,367).

The reference of O'Dell et al. has been discussed above.

Claims differ by reciting shapes of the heat transfer surfaces that are not disclosed by the reference of O'Dell et al.

The references of Douglas-Hamilton and Peterson both disclose that it is known in the art of preserving and transporting biological material to provide complementary heat transfer surfaces between the material housing and the transport container (See elements 32 and 34 of Douglas-Hamilton and elements 2 and 11 of Peterson).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art to provide heat transfer surfaces that are complementary between the biological material holding container and outer transport container so as to provide efficient heat exchange between the cooling source and the material holding container. With respect to the shape of the surfaces, it would have been obvious to one of ordinary skill in the art to provide surfaces within the transport container that match the surfaces of the material holding container while maintaining the transfer efficiency of the system. Note, changes in shape are not a patentable distinction (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)).

7. Claims 14, 38, 39 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dell et al.(US 5,385,821) in view of Reviel (US 3,713,302).

The reference of O'Dell et al. has been discussed above.

Claims 14, 38, 39 and 53 differ by reciting that the device includes a heater.

The reference of Reviel discloses that it is known in the art of cooling to employ a thermo-electric cooling source that can function as a cooling source or a heating source (See column 2, lines 2-22).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a thermo-electric device in the system of the primary reference for the known and expected result of providing improved temperature control when compared to the use of ice or ice packs (See column 1, lines 35-55).

8. Claims 22, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dell et al.(US 5,385,821) in view of McKelvey et al.(EP 0 376 763).

The reference of O'Dell has been discussed above.

Claims 22, 36 and 37 differ by reciting that the portable housing is placed within a perfusion device.

The reference of McKelvey et al. discloses a system for holding an organ of during perfusion, storage and transport of the organ, comprising: a portable housing (31) for holding the organ; an organ perfusion apparatus (30) adapted to receive the portable housing and the portable housing is configured (1) to hold the organ independently from either of the organ perfusion apparatus, (2) to be separately received by the organ perfusion apparatus for perfusion of the organ, and (3) to allow perfusion, storage, and transport of the organ without removal of the organ from the portable housing.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to position the portable housing of the primary reference within a perfusion system as suggested by the reference of McKelvey et al. for the known and expected result of allowing the organ to be perfused without compromising the sterility of the organ supported within the portable housing.

With respect to claims 36 and 37, the reference of McKelvey et al. discloses the use of tubes that pass through the portable housing to be connected to the perfusion system (See Figure 5).

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dell et al.(US 5,385,821) in view of McKelvey et al.(EP 0 376 763) and Fahy et al.(WO 96/29865).

The combination of the references of O'Dell and McKelvey et al. has been discussed above.

Claim 21 differs by reciting that the system includes a diagnostic device adapted to receive the housing.

The reference of Fahy et al.('865) discloses that it is conventional in the art to provide an organ perfusion system that is capable of evaluating the organ that is perfused within the device (See the abstract).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an additional system that is compatible with the organ housing for providing evaluation of the organ as suggested by the reference of Fahy et al.('865). Construction of the device such that the organ housing can be interfaced with the system without removal of the organ from the housing would have been obvious for the known

and expected result of allowing the organ to be interfaced with a plurality of systems without being exposed to the environment and/or contaminated from unnecessary handling.

Response to Arguments

10. With respect to provisional objection of claims 40-58 to under 37 CFR 1.75 as being a substantial duplicate of claims 1-19, Applicants argue that claims 1-19 are drawn to “an apparatus” while claims 40-58 are drawn to “a system” and therefore are not duplicate claims (See page 10 of the response filed 4/9/2008).

In response, Applicants’ comments are not found to be persuasive because it is not clear what structural differences, if any, exist between a claimed identified as “an apparatus” verses a claim identified as “a system” when the rest of the claim language is identical. It is noted that Applicants’ comments are silent with respect to this difference, if any at all.

11. With respect to the rejection of Claims 1-7, 12, 13, 15-20, 23-27, 31, 32, 33, 40-46, 51, 52 and 54-58 under 35 U.S.C. 102(b) as being anticipated by O’Dell et al.(US 5,385,821), Applicants argue that the rejection is improper because the reference of O’Dell et al. does not disclose “an organ or tissue support surface configured to support an organ or tissue within said portable housing”. Applicants stress that it is unreasonable to assert that either the bottom surface of preservation device (98) or element (14) of the device of O’Dell et al. can be considered to correspond to an organ or tissue supporting surface configured to support an organ or tissue within said portable housing. Applicants stress that element (14) is flexible and

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therefore cannot be considered to be a support surface (See pages 10-12 of the response filed 4/9/2008).

In response, Applicants' comments are not found to be persuasive because whether or not the bottom wall (14) is flexible, it is still considered capable of supporting an organ or tissue within the device. Especially since the instant claim language fails to further define the structure encompassed by the language "an organ or tissue support surface configured to support an organ or tissue within said portable housing". The Examiner further asserts that elements (15) and (13) of the device of O'Dell et al. can be considered structures that would also meet the instant claim language.

Applicants further argue that the claims require a portable housing and an organ or tissue supporting surface (See pages 11-12 of the response filed 4/9/2008).

In response, for the same reasons set forth immediately above, the Examiner is of the position that the reference of O'Dell et al. meets the instant claim language. It is noted that the instant claim language does not preclude the bottom wall (14) or elements (15) and (13) of the reference of O'Dell et al. from meeting the instantly claimed support surface. It is noted that the features upon which applicant relies (i.e., the structures shown in Figures 4C and 4D of the instant application) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. With respect to the 35 USC 103 rejections of record including the combination of the reference of O'Dell et al. with the references of Douglas-Hamilton, Peterson, Reviel, McKelvey

and Fahy, Applicants assert that these references fail to make-up for the shortfalls in the application of O'Dell et al. to the subject matter of independent claims 1, 20 and 40 (See page 12 of the response dated 4/9/2008).

In response, the Examiner maintains that the rejections are proper for the same reasons as set forth above with respect to the rejection of the claims under 35 USC 102. The additional references of Douglas-Hamilton, Peterson, Reviel, McKelvey and Fahy have been cited to address additional claim limitations recited in some of the dependent claims.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM H. BEISNER whose telephone number is (571)272-

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1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/William H. Beisner/
Primary Examiner
Art Unit 1797**

WHB